PANA0001-100
(formerly PANA-0002)

PATENT APPLICATION

REMARKS

Status of the Claims

Claims 1-8, 10-20, 22, 31 and 43-60 were pending in the application prior to filing the Request for Continued Examination.

Claims 1-8, 10-20, 22, 31 and 43-60 were rejected.

By way of this amendment, claims 1-8, 10-20, 22 and 31 have been canceled, claim 48 is amended and new claims 61-79 have been added.

Upon entry of this amendment, claims 43-79 will be pending.

Summary of the Amendment

Claims 1-8, 10-20, 22 and 31, which are directed to aspects of the invention which Applicant intends to pursue in a continuation application, have been canceled without prejudice.

Claim 48 has been amended to correct an error that occurred when Applicant inadvertently did not delete language that was replaced by language added in the amendment dated March 28, 2005.

New claim 61 corresponds to the subject matter in claim 48 that includes treatment of individuals who has been exposed to ionizing radiation. New claims 62-68 are dependent of new claim 61 and similarly correspond to claims 49-52, 55 and 56.

New claim 70 corresponds to the subject matter in claim 48 that includes treatment of individuals who has been exposed to a chemical mutagen. New claims 71-77 are dependent of new claim 70 and similarly correspond to claims 49-52, 55 and 56.

New claims 69, 78 and 79 refer to methods which employ autologous DNA derived prior to exposure to the mutagenic stimuli from the individual who is being treated. Support for new claims 69, 78 and 79 is found throughout the specification, particularly at page 12.

No new matter has been added.

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Prior Objection

An objection was made to claim 48 for containing informalities. The claim contained a grammatically incorrect phrase. The phrase, which was intended to have been deleted in the earlier amendment, has been deleted.

The claim no longer contains the informality upon which the objection was made. The objection should be withdrawn in view of the amendment. Applicant respectfully requests that the rejection be withdrawn.

Rejection under 35 U.S.C. § 112

Claims 48-57 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In Applicant's amendment dated March 28, 2005, Applicant inadvertently did not delete the phrase "does not cancer." Claims 48 has been amended to delete phrase. As amended, the claims 48-57 are in compliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully requests that the rejection of claims 48-57 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Claims 48-52 and 54-57 were under 35 U.S.C § 112, first paragraph, because it was asserted that while being enabled for treating an individual exposed to ionizing radiation, it is asserted that the specification does not enable methods for treating individuals exposed to other stimuli. It is asserted that specification does not enable one skilled in the art to which it pertains or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant respectfully disagrees.

It is well established that Applicant's assertions of enablement must be accepted as true unless the Examiner can present evidence or reasoning that would lead one skilled in the art to question the objective truth of the assertions. In this case, the Examiner has not met this burden and the totality of evidence on the record supports conclusion of enablement.

The Examiner's reasons for questioning the enablement of the embodiments not related to exposure to ionizing radiation are that Examiner doubts the unclaimed possible

mechanism for action, that no other mechanism is proposed and the specification lacks working examples. The Examiner asserts that the reasons offered are sufficient to conclude that the objective truth of Applicant's assertions are in doubt.

The totality of evidence of record contradict the Examiner's conclusions. First, there is no requirement that Applicant's provide a description of the mechanism by which the invention will work. The Examiner may not simply conclude that the objective truth of Applicant's assertions are in doubt because no mechanism is provided. Second, the Examiner has not offered any evidence or reasoning why the claimed invention will work; only that he doubts homologous recombination will work. No evidence has been provided to support the assertion that one skilled in the art would not believe that genomic DNA cannot be used to prevent or treat diseases or disorders associated with exposure to mutagenic stimuli other than ionizing radiation such as chemical mutagens. Finally, Applicant has submitted data in the form of a declaration filed pursuant to 37 CFR 1.132 on April 25, 2003 which contains data showing that mice exposed to the chemical mutagen cyclophosphamide were effectively treated with genomic DNA according the claimed invention (see Paragraph 8 (page 4) and Exhibit 5 of the Declaration of Leonid A. Yakubov).

The evidence and reasoning presented is references are asserted to raise doubts as to the theorized mechanism stated in the specification. The specification indicates that Applicant was not limited to such a theory and the claims do not have any requirement that homologous recombination occurs. There is no requirement that an Applicant provide any explanation as to how the invention works and it is improper to reject a claim not limited to a mechanism of action because of asserted evidence that an unclaimed mechanism may be incorrect. The evidence and reasoning provided by the Examiner is not directed to the claimed invention. In fact, the totality of evidence of record strongly supports a finding of enablement. The Examiner has not met the legal burden required to support an enablement rejection of claims 48-52 and 54-57.

The Examiner cites *Ex Parte Sudilovsky*, 21 USPQ2d 1702 (BPAI), *In re Novak*, 134 USPQ 335 (CCPA 1962) and *In re Fouche*, 169 USPQ 429 (CCPA 1971) in support

of his conclusion. of a finding of non-enablement based upon the evidence of record. Applicants not that among the differences between the present application *Sudilovsky*, a most important difference is that the present invention is supported by evidence submitted in the form of a Declaration under 1.132 while no evidence was present in *Sudilovsky*. *Novak* relates to rejections under 35 U.S.C. 101 while the claims at issue here were rejected under 35 U.S.C. 112, first paragraph. Unlike the present application, the record in *Fouche* included reasoning and evidence to support the conclusion that one skilled in the art would question the operability of the invention.

In the present application, no evidence is provided to support a conclusion that one skilled in the art would not accept Applicant's assertions of enablement. The reasoning provided by the Examiner is specifically directed at the conclusion that one skilled in the art would not accept homologous recombination as a possible mechanism of action. However, the claims do not require homologous recombination. Applicant's assertion of enablement is supported by evidence in the record. Such evidence of supports the conclusion that the invention as claimed in claims 48-52 and 54-57 is enabled. Applicant respectfully requests that the rejection of claims 48-52 and 54-57 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Prior Rejection under 35 U.S.C. § 102

Claims 43-53 and 56-60 were rejected under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious in view of Sekiguchi et al. (US 3,803,116).

Sekiguchi et al. disclose a method of treating cancer patients who are being treated with ionizing radiation by administering to such individuals low molecular weight DNA derived from non-human sources such as fish sperm or non-human mammalian organ DNA. Sekiguchi et al. specifically discloses that because the DNA is non-human, in order to avoid "hereditary danger of genetic mutation" the non-human DNA should be lower molecular weight (200,000-500,000). As the Examiner has indicated, 200K-500K is about 300-800 basepairs of foreign DNA. Nothing is Sekiguchi teaches or suggests the

use of 300-800 basepairs of human DNA. The motivation for using "lower molecular weight DNA" instead of high molecular weight DNA arises from Sekiguchi's conclusion that using high molecular weight foreign DNA was dangerous and that foreign DNA had to be reduced in size. Sekiguchi in fact teaches away from using human DNA at the size 300-800 basepairs.

Applicant respectfully notes that the evidence of record shows an improved result when using DNA from the same species within the claimed size range versus the results seen when using DNA from a different species within the claimed size range. In the Declaration of Leonid A. Yakubov filed pursuant to 37 CFR 1.132, the data in Paragraph 7 (page 3-4) and Exhibit 4 shows improved survival using mouse DNA versus non-mouse DNA to treat irradiated mice. The data in Paragraph 8 (page 4) and Exhibit 5 shows improved survival using mouse DNA versus non-mouse DNA to treat exposure to the chemical mutagen cyclophosphamide.

Claims 43-53 and 56-60 are neither anticipated by Sekiguchi et al. nor obvious in view of it. Applicant respectfully requests that the rejection of claims 43-53 and 56-60 under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious in view of Sekiguchi et al. (US 3,803,116) be withdrawn.

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Conclusion

In view of the foregoing, Applicant submits that the claims as amended are in condition for allowance, and an early Office Action to that effect is earnestly solicited. Applicant invites the Examiner to contact the undersigned at (215) 665-6928 to clarify any unresolved issues raised by this response.

Respectfully submitted,

Mark DeLuca.
Registration No. 33,229

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COZEN O'CONNOR, P.C.
1900 Market Street
Philadelphia, PA 19103-3508
Telephone: (215) 665-5592
Facsimile: (215) 701-2027